REMARKS

Reconsideration an d withdrawal of the rejections of the application are respectfully requested in view of the remarks and amendments herein.

I. STATUS OF THE CLAIMS AND FORMAL MATTERS

Claims 1-7, 9-11, 21, 23, 25-30 and 32-37 are pending. Claims 1, 9, 11, 21, 25 and 27 have been amended, new claims 32-37 have been added, and claims 8, 12-20, 22, 24 and 31 have been cancelled, without prejudice, without admission, without surrender of subject of matter, and without any intention of creating any estoppel as to equivalents.

No new matter is added.

It is submitted that these claims, as originally presented, are in full compliance with the requirements of 35 U.S.C. 112. The new claims, as presented herein, are not added for the purpose of patentability within the meaning of 35 U.S.C. §§101, 102, 103 or 112. Rather, these claims are added for clarification and to round out the scope of protection to which Applicants are entitled.

Specifically, support for claims 32-37 may be found on page 3, lines 15 to 32.

I. THE OBJECTIONS TO THE CLAIMS ARE OVERCOME

Claim 25 was objected to because of a misspelling. Applicants respectfully traverse the objections. It is respectfully submitted that the amendment of claim 25 renders the objection moot. Consequently, reconsideration and withdrawal of the objections to the claims are respectfully requested.

II. THE REJECTIONS UNDER 35 U.S.C. §112 ARE OVERCOME

Claim 9 was rejected under 35 U.S.C. §112, second paragraph, as allegedly being incomplete for omitting essential steps. Applicants respectfully traverse the rejections. It is respectfully submitted that the amendment of claim 9 renders the objection moot. Consequently, reconsideration and withdrawal of the rejection to the claim under 35 U.S.C. §112, second paragraph, is respectfully requested.

Claims 1-11, 21, 23, and 25-30 were rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite. The rejection is respectfully traversed.

Specifically, the Office Action states that it is unclear what the metes and bounds are for the claimed subject matter. Applicants respectfully disagree.

Claim 1 has been amended to recite that the epitopes comprise specific SEQ ID NOs, and that the epitopes comprise a stretch of 6 amino acids. Accordingly, the metes and bounds of the claims are adequately described, rendering the claims definite.

Furthermore, as is known to one of skill in the art, a "T-cell epitope" (or: "T-lymphocyte epitope") is a peptide which is able to bind to an MHC molecule and which stimulates T-cells in an animal species. Preferred T-cell epitopes are "promiscuous" (or "universal" or "broad-range") epitopes, *i.e.* epitopes which bind to a substantial fraction of a particular class of MHC molecules in an animal species or population. Furthermore, T-cell epitopes of Ag85B and ESAT-6 are well known in the art, including in the documents referenced in the instant application on page 4, lines 14 to 15, which include, *inter alia*, Ravn *et al.* (1999) (included on the March 18, 2003 IDS). In fact, Ravn *et al.* demonstrates the ability of ESAT-6 to stimulate T-cells in humans, thereby classifying ESAT-6 as containing mutiple T-cell epitopes. Furthermore, the methods by which this was determined, i.e. the separation and culture of peripheral blood mononuclear cells (PBMC) from individuals infected with *M. tuberculosis*, *in vitro* stimulation of the PMBC with ESAT-6, and testing of the supernatants for IFN-γ by ELISA, may be easily performed by one of skill in the art in order to determine the presence of an epitope. Such testing would not entail an undue burden on the skilled artisan as such testing is quite routine and is frequently utilized by those of skill in the art for the determination of epitope sites.

The methods described in Ravn *et al.* may be used with systematically overlapping peptides from immunogenic proteins which are tested for their ability to stimulate T-cells. Furthermore, T-cell epitopes may be determined through the use of "reverse" immunogenics, as described in Immunobiology, 5th Ed. (Janeway et al., 2001). Briefly, "reverse" immunogenics involves identifying self nonapeptides from a known reactive peptide, synthesis of the candidate nonapeptides, assaying the target MHC molecule in the presence of the candidate nonapeptides to determine whether the MHC molecule could form correctly in the presence of the nonapeptide, and testing those nonapeptides which do allow correct assembly of the MHC molecule for their ability to stimulate T-cells (see Immunobiology, pg. 586).

Accordingly, one of skill in the art would readily know and understand whether a given sequence constitutes a T-cell epitope, further demonstrating that the claims are definite.

Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §112, second paragraph, of the application are respectfully requested.

Additionally, claims 8, 9, 11, 25, and 27 were rejected under 35 U.S.C. §12, first paragraph, as allegedly lacking enablement for a vaccinating agent constructed from *M. tuberculosis* proteins which cross-protect against any other species of the genus *Mycobacterium*. Applicants respectfully traverse the rejection.

As previously stated, Applicants respectfully note that ESAT6 and Ag85B proteins are well-conserved within the species of the *mycobacterium* complex. Indeed, ESAT6 and Ag85B amino acid sequences are identical between *M. tuberculosis* and *M. bovis*.

However, in an effort to further prosecution, Applicants have amended the present vaccination claims to specify vaccination against *M. tuberculosis*.

Applicants notes that the immunogenic and pharmaceutical composition claims were not rejected for lack of enablement, and have not limited these claims to *M. tuberculosis*. Indeed, Applicants further note that the term "immunogenic composition" has the definition ascribed to it in the art, namely that "immunogenic or immunological composition" covers any composition that elicits an immune response against the targeted pathogen; for instance, after administration or injection into the animal, elicits an immune response against the targeted pathogen (e.g., mycobacterium).

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of all the rejections to the claims under 35 U.S.C. §112.

CONCLUSION

In view of the remarks and amendments herein, the application is now in condition for allowance. Consequently, reconsideration and withdrawal of the rejections, and prompt issuance of a notice of allowance, are respectfully requested.

Respectfully submitted,

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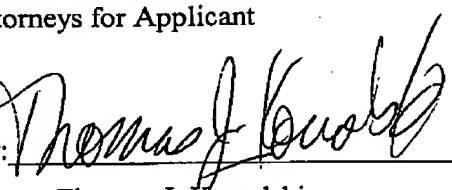
By: 

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